

## **REMARKS**

Reconsideration of the subject application as amended herein is respectfully requested. The Examiner has rejected claims under 35 U.S.C. §§ 112, 102 and 103. The Applicant hereby requests that these rejections be withdrawn.

### **A. Rejections of claims 2, 18, 34, 38, 47 and 48 under 35 U.S.C. § 112, ¶ 1**

The Examiner has rejected these claims as failing to comply with the written description requirement. The Examiner contends that the phrase "leak independent" is not disclosed in the application to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention.

The Applicant respectfully disagrees. The application specifically discloses that pre-ferred effort sensors are independent of leak, and the specified examples of sensors could certainly enable one skilled in the art to practice the invention. For example, the application expressly provides:

In the invention, the device combines additional fuzzy inference rules based upon an effort signal from an effort sensor. The effort sensor is not dependent on measured airflow and as such is immune to errors associated with leak.

Specification, p. 4, line 33 to p. 5, line 1.

In the preferred embodiment, the effort sensor is a suprasternal notch sensor. However, alternative embodiments of the invention may utilize other effort sensors including, for example, an esophageal pressure sensor or an electromyograph.

Specification, p. 5, lines 20-22.

Given the statements in the application, those skilled in the art would understand that the invention is disclosed and has been enabled. Accordingly, Applicant submits that the language of the claims complies with 35 U.S.C. § 112.

**B. Rejections of claims 1-2, 9-10, 17-34 and 37-46 under 35 U.S.C. § 102**

All the claims recite a method or apparatus providing synchronized ventilation based on the instantaneous phase of respiration of the patient. As is well known in the art, and as described in some of the claims (see, e.g., claim 41), the phase of respiration is measured as a fraction of a respiration cycle. Some of the claims (see, e.g., claim 1) have been amended to recite that the instantaneous phase of respiration is determined continuously at least during inspiration.

In order to be anticipatory, Banner must disclose a synchronized ventilation method or apparatus that makes use of the instantaneous phase of respiration in the manner recited by the claims. However, a careful review of Banner reveals that not only does Banner fail to disclose anywhere that synchronized ventilation can be accomplished using the instantaneous phase of respiration, but, in fact, Banner fails to disclose determining the instantaneous phase of respiration at all! Banner also fails to disclose determining the instantaneous phase of respiration continuously at least during inspiration, as required by some of the claims.

Banner describes a synchronous ventilation method and apparatus that uses the work of breathing (WOB) as a control parameter. This parameter is measured in

joules/liter and is determined by averaging pressure over several breathing cycles (see Fig. 7). WOB indicates how much energy is a patient using, on the average, for each liter of air that he breathes. The Examiner takes the position that “ the incremental management assessment of WOB methodology” somehow equates with “the generation of the instantaneous respiratory phase” (See page 3, last paragraph). The Applicant fails to see how the assessment of a parameter measured in joules/liter and averaged over several breathing cycles bears any relation whatsoever to an instantaneous phase parameter measured as a fraction of one breathing cycle.

Accordingly, it is respectfully submitted that Banner fails to disclose an apparatus or method in which the instantaneous phase of respiration is determined and used in the manner recited by the claims and therefore this reference fails to anticipate these claims.

### **C. Rejections of claims 3-8, 12-15, 35-36 and 47-48 under 35 U.S.C. § 103**

These claims have been rejected as being obvious over Banner in view of Schmidt et al (Schmidt) or Spin. As discussed above, all the claims require determining the instantaneous phase of respiration. Banner fails to teach this limitation. The Examiner relies on Schmidt for teaching a respiration device with fuzzy logic and on Sipin for disclosing an external pressure sensor. But, since all the claims require the determination of the instantaneous phase of respiration and since the Examiner does not even rely on Schmidt or Spin to teach this limitation, it is respectfully submitted that the combination of Banner and Schmidt or Banner and Spin fail to render the claims obvious.

Additionally, Schmidt discloses a flow triggering respiration sensor (col. 9, line 28 - col. 10, line 9). Banner takes the position that flow based triggering is inherently inadequate (col. 28, line 34). Therefore, Banner clearly teaches away from the use of flow based triggering, and it cannot be combined with Schmidt. *Tec Air Inc. v. Denso Manufacturing Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999).

#### **D. New Claim 49**

As noted by the Examiner, Banner teaches the control of ventilatory support by using WOB only during the inspiratory cycle of the patient. The present invention as defined in new claim 49 includes the step of determining the instantaneous phase of respiration of the patient during both the inspiration and expiration cycles. Moreover, ventilation is delivered to the patient in accordance with the desired pressure value during the patient's inspiration and expiration cycles. Neither of these features is in the prior art, and, accordingly, new claim 49 is in condition for allowance.

In summary, it is respectfully submitted that none of the cited references discloses the determination of the instantaneous phase of respiration. Since this limitation is found in all the claims, it is respectfully submitted that the references fail to anticipate or obviate the invention as claimed and therefore the application should be allowed.

Respectfully submitted,

GOTTLIEB, RACKMAN & REISMAN, P.C.

A handwritten signature in black ink, appearing to read 'Tiberiu Weisz', with a stylized, cursive script.

Tiberiu Weisz  
Reg. No. 29,876